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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
NGUYEN, HUONG Q	

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3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/732,843	CICENAS ET AL.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-13 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-13 and 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 3/19/2009. Claims 1, 16, and 17 are amended. It is noted that the previous claim objections are also overcome. Claim 10 is cancelled. **Claims 1-9, 11-13, and 16-22** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1-9, 11-13, and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (US Pat No. 5526822) in view of Banik et al (US Pat No. 6053877), further in view of Bryan et al (US Pat No. 6488636).

4. In regards to **Claim 1**, Burbank et al disclose a biopsy device comprising of a hollow biopsy needle (44) having a tissue receiving port (46), a hollow cutter (68) advanceable within the biopsy needle to sever tissue received within the tissue receiving port, wherein the cutter has a sidewall surrounding an interior, and a sampling mechanism including "tubular knockout pin" (92) having an open distal end sized for receiving a tissue sample severed by the hollow cutter and advanceable within the cutter (Col.13: 38-41).

5. However, Burbank et al do not explicitly disclose said sampling mechanism is a sample tube being releasably supported on the biopsy device such that the sample tube and at least one

tissue sample stored therein may be removed form the biopsy device without disassembling the biopsy device, nor does Burbank et al disclose the cutter has a plurality of holes spaced from the distal end of the cutter and positioned for providing vacuum axially through the cutter when multiple tissue samples are disposed within the sample tube within the cutter.

6. Banik et al disclose an effective sampling mechanism comprising a sample tube 20 advanceable within a hollow cutter 14, the sample tube having with an open distal end sized for receiving a tissue sample severed by the hollow cutter, the sample tube being releasably supported on the device such that the sample tube and at least one tissue sample stored therein may be removed from the device without disassembling the device (Col.10: 3-17), best seen in Figures 2 and 5D, as an effective sampling mechanism that advantageously allows collection of multiple samples at one time.

7. Burbank et al also disclose a biopsy device wherein a hollow biopsy needle 644 with a tissue receiving port 646 has a plurality of holes 650 spaced from the distal end and are positioned for providing vacuum axially through the hollow biopsy needle by way of vacuum chamber 652, best seen in Figure 16 (Col.19: 24-35), to effectively draw in larger and more uniform samples.

8. Bryan et al disclose an analogous biopsy device comprising basket tube 18 with a sidewall surrounding an interior, the basket tube having a plurality of holes 114 spaced from the distal end, wherein the plurality of holes are formed transversely through the sidewall for providing fluid communication from a region exterior to the side of the basket tube to the interior, and wherein the holes are positioned for providing vacuum axially through the basket

tube, best seen in Figure 2-4, 12, and 14-15, to effectively provide axial vacuum through a tube positioned between two other tubes 16, 24 of the biopsy device.

9. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy device of Burbank et al to have a sampling mechanism comprising a sample tube advanceable within the hollow cutter, the sample tube having with an open distal end sized for receiving a tissue sample severed by the hollow cutter, and the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device, as taught by Banik et al, as an effective sampling mechanism that advantageously allows collection of multiple samples at one time.

10. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Burbank et al and Banik et al such that the cutter, similarly place between the two tubes of the hollow needle and the sample tube, has a plurality of holes spaced from the distal end of the cutter, wherein the plurality of holes are formed transversely through the sidewall for providing fluid communication from a region exterior to the side of the basket tube to the interior, and wherein the holes are positioned for providing vacuum axially through the cutter, as taught by Bryan et al, to effectively provide axial vacuum through the cutter as placed between the hollow needle and the sample tube and promote drawing in of the tissue samples even when multiple tissue samples are disposed within the sample tube within the cutter.

11. However, Burbank et al in combination with Banik et al and Bryan et al do not explicitly disclose the sample tube comprises a vacuum lumen and a sample lumen. However, Burbank et

al do disclose a biopsy device comprising a hollow biopsy needle 644 that comprises a vacuum lumen 652 and a sample lumen 646 wherein the vacuum lumen extends along side of at least a portion of the sample lumen, best seen in Figure 16, to effectively provide uniform vacuum to draw in larger and more uniform tissue samples (Col.19: 24-35). Thus Burbank et al teach the importance of a vacuum lumen extending along side a sample lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sample tube of Burbank et al as modified by Banik et al and Bryan et al to comprise both a vacuum lumen and a sample lumen, wherein the vacuum lumen extends along side of at least a portion of the sample lumen, as taught by Burbank et al, to effectively provide uniform vacuum to draw in the tissue samples.

12. In regards to **Claim 2**, Banik et al disclose the sample tube is adapted to store multiple samples in an end to end configuration, best seen in Figure 5d.

13. In regards **Claim 3**, Burbank et al, Banik et al, and Bryan et al disclose a vacuum source in communication with the sample tube as defined above (Burbank et al Col.14, line 47-50).

14. In regards to **Claims 4-6**, Burbank et al and Banik et al disclose the sample tube as defined above advanced by a pneumatic cylinder (Burbank et al Col.14, line 40-43).

15. In regards to **Claim 7**, Burbank et al disclose an apparatus for advancing and retracting the cutter (68) within the biopsy needle. Specifically, Burbank et al disclose an "inner cutter linear driver" (88) to move the cutter proximally and distally, best seen in Figure 2 (Col.14, line 61-64).

16. In regards to **Claim 8**, Burbank et al and Banik et al disclose an apparatus for advancing and retracting the sample tube as defined above within the cutter (68), referred to as "tubular knock out pin linear driver" (112), best seen in Figure 2 (Burbank et al Col.14, line 40-43).

17. In regards to **Claim 9**, Burbank et al disclose the hollow needle (44) comprising a lateral tissue receiving port (46) spaced from the distal end of the needle, best seen in Figure 4.

18. In regard to **Claims 11-12**, Banik et al disclose the sample tube 20 comprises a tube wall feature such as notch or indentation 32, 32' adjacent the distal end of the sample tube, best seen in Figure 2.

19. In regards to **Claim 13**, Burbank et al disclose a rotating journal for rotating and advancing the cutter. The rotating journal is defined as the "cannular inner cutter elongate indexing gear" (72), which is connected to "cannular inner cutter drive motor" (80) and "inner cutter linear driver" (88) to rotate and advance the cutter, respectively, best seen in Figure 2 (Col.13, line 28-37; Col.18 line 22-24).

20. In regards to **Claim 16**, Burbank et al disclose a biopsy device comprising:

a hollow biopsy needle (44) having a closed distal end and a lateral tissue receiving port (46);

a hollow cutter (68) having an open distal end, a lumen extending proximally from the open distal end, and the cutter advanceable within the biopsy needle to sever tissue received within the tissue receiving port;

a sampling mechanism including "tubular knock out pin" (92) having an open distal end defining a distal opening, said tubular knock out pin advanceable within the cutter;

a drive mechanism for advancing and rotating the cutter within the biopsy needle, best seen in Figure 17 (Col.19, line 49-67);

an advancement assembly for the sampling mechanism comprising tubular knock out pin motor 104, gear 96, 100, drive chamber 32, and linear driver 112, best seen in Figure 2, operable to advance the tubular knock out pin distally within the cutter to store a tissue sample after the cutter has been advanced within the needle to sever the tissue sample, best seen in Figure 6.

21. However, Burbank et al do not explicitly disclose said sampling mechanism is a sample tube releasably supported on the biopsy device. Banik et al disclose an effective sampling mechanism comprising a sample tube 20 advanceable within a hollow cutter 14, the sample tube having with an open distal end sized for receiving a tissue sample severed by the hollow cutter, the sample tube being releasably supported on the device such that the sample tube and at least one tissue sample stored therein may be removed from the device without disassembling the device (Col.10: 3-17), best seen in Figures 2 and 5D, as an effective sampling mechanism that advantageously allows collection of multiple samples at one time.

22. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy device of Burbank et al to have a sampling mechanism comprising a sample tube advanceable within the hollow cutter, the sample tube having with an open distal end sized for receiving a tissue sample severed by the hollow cutter, and the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the

biopsy device, as taught by Banik et al, wherein in combination the advancement assembly is operable to advance the sample tube distally within the cutter to store a tissue sample within the sample tube after the cutter has been advanced within the needle to sever the tissue sample, as an effective sampling mechanism that advantageously allows collection of multiple samples at one time.

23. Burbank et al in combination with Banik et al also do not disclose a plurality of holes extending through a wall of the cutter. It is noted that Burbank et al do disclose a biopsy device wherein a hollow biopsy needle 644 with a tissue receiving port 646 has a plurality of holes 650 spaced from the distal end and are positioned for providing vacuum axially through the hollow biopsy needle by way of vacuum chamber 652, best seen in Figure 16 (Col.19: 24-35), to effectively draw in larger and more uniform samples.

24. Bryan et al disclose an analogous biopsy device comprising basket tube 18 with a sidewall surrounding an interior, the basket tube having a plurality of holes 114 spaced from the distal end, wherein the plurality of holes are formed transversely through the sidewall for providing fluid communication from a region exterior to the side of the basket tube to the interior, and wherein the holes are positioned for providing vacuum axially through the basket tube, best seen in Figure 2-4, 12, and 14-15, to effectively provide axial vacuum through a tube positioned between two other tubes 16, 24 of the biopsy device.

25. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Burbank et al and Banik et al such that the cutter, similarly place between the two tubes of the hollow needle and the sample tube, has a plurality of holes extending through a wall of the cutter, wherein the plurality of holes are formed

transversely through the sidewall for providing fluid communication from a region exterior to the side of the basket tube to the interior, and wherein the holes are positioned for providing vacuum axially through the cutter, as taught by Bryan et al, to effectively provide axial vacuum through the cutter as placed between the hollow needle and the sample tube and promote drawing in of the tissue samples even when multiple tissue samples are disposed within the sample tube within the cutter.

26. However, Burbank et al in combination with Banik et al and Bryan et al but do not explicitly disclose the sample tube comprises a vacuum lumen and a sample lumen. However, Burbank et al do disclose a biopsy device comprising a hollow biopsy needle 644 that comprises a vacuum lumen 652 and a sample lumen 646 wherein the vacuum lumen extends along side of at least a portion of the sample lumen, best seen in Figure 16, to effectively provide uniform vacuum to draw in larger and more uniform tissue samples (Col.19: 24-35). Thus Burbank et al teach the importance of a vacuum lumen extending along side a sample lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sample tube of Burbank et al as modified by Banik et al and Bryan et al to comprise both a vacuum lumen and a sample lumen, wherein the vacuum lumen extends along side of at least a portion of the sample lumen, as taught by Burbank et al, to effectively provide uniform vacuum to draw in the tissue samples.

27. **Claims 17-20 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al in view of Banik et al.

28. In regards to **Claim 17**, Burbank et al disclose a method of obtaining a tissue sample comprising the steps of:

drawing tissue into a tissue receiving port (46) of a hollow biopsy needle (44);

advancing a hollow cutter (68) in the needle to sever a tissue sample and to encapsulate the severed tissue sample within the cutter upon reaching a distalmost position with the hollow biopsy needle, wherein the cutter closes the tissue receiving port when the cutter is at the distalmost position;

a sampling mechanism including knock out pin (92) (Col.17: 48-51), wherein said knock out pin is moved after the cutter has reached the distalmost position and after the cutter has encapsulated the severed tissue sample, best seen in Figure 6.

29. However Burbank et al do not explicitly disclose the sampling method comprising the step of advancing a hollow sample tube in the cutter to position the tissue sample in the sample tube, wherein the tissue sample is axially received in the hollow sample tube through an open distal end during the act of advancing the hollow sample tube, and then removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube.

30. Banik et al disclose an effective sampling mechanism comprising a hollow sample tube (20) with an open distal end, wherein the hollow sample tube is advanced in a hollow cutter (14) to position a tissue sample in the sample tube, wherein the tissue sample is axially received in the hollow sample tube through the open distal end during the act of advancing the hollow sample tube (Col.6: 37-48), and then removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube (Col.10: 3-17), as an effective sampling mechanism that allows collection of multiple samples at one time, best seen in Figures 2 and 5D.

Banik et al also disclose that the sample tube is advanced about at the same time as jaws 14, 14' sever a tissue sample (Col.6: 43-48) because the sample tube cannot be advanced prior to the tissue sample being severed.

31. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the sampling mechanism of Burbank et al with the sampling mechanism of Banik et al such that a hollow sample tube is advanced in the cutter with the distal end of the hollow cutter disposed in the needle, to position the tissue sample in the sample tube, the tissue sample axially received in the hollow sample tube through an open distal end during the act of advancing the hollow sample tube, and then removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube, wherein in combination it would also be obvious that at least a portion of the act of advancing the hollow sample tube is performed after the cutter has reached the distalmost position and has encapsulated the severed tissue sample to effectively capture the tissue after severance, as an equally as effective sampling mechanism that also advantageously allows the simultaneous collection of multiple samples.

32. However, Burbank et al in combination with Banik et al do not explicitly disclose the sample tube comprises a vacuum lumen and a sample lumen. However, Burbank et al do disclose a biopsy device comprising a hollow biopsy needle 644 that comprises a vacuum lumen 652 and a sample lumen 646 wherein the vacuum lumen extends along side of at least a portion of the sample lumen, best seen in Figure 16, to effectively provide uniform vacuum to draw in larger and more uniform tissue samples (Col.19: 24-35). Thus Burbank et al teach the importance of a vacuum lumen extending along side a sample lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the

sample tube of Burbank et al as modified by Banik et al to comprise both a vacuum lumen and a sample lumen, wherein the vacuum lumen extends along side of at least a portion of the sample lumen, as taught by Burbank et al, wherein the method comprises providing vacuum to the sample tube vacuum lumen to effectively provide uniform vacuum to draw in the tissue samples.

33. In regards to **Claim 18**, Banik et al disclose stacking multiple samples in an end to end configuration within the sample tube, best seen in Figure 5D.

34. In regards to **Claim 19**, Burbank et al in combination with Banik et al disclose a method comprising providing a vacuum through a sample tube (578) (Burbank et al Col.15, line 6-8, also Col.14, line 47-50). Banik et al also disclose providing vacuum through the sample tube to remove samples (Col.10: 23-25)

35. In regards to **Claim 20**, Burbank et al in combination with Banik et al disclose a method comprising providing axial vacuum in the cutter through the sample tube with at least one sample disposed the sample tube for the reasons elaborated above.

36. In regards to **Claim 22**, Burbank et al in combination with Banik et al disclose the sample tube remains stationary during the act of advancing the hollow cutter as explained above.

37. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al, Banik et al, and Bryan et al, further in view of Terwilliger (US Pat No. 5183052).

38. Burbank et al in combination with Banik et al and Bryan et al disclose the invention above but do not disclose the sample tube advancement assembly comprises a vacuum chamber and a floating piston. Terwilliger teaches that it is well known to use a vacuum chamber and floating piston to effectively advance the cannula of an analogous biopsy device to sample tissue (Col.3: 11-23; Col.5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Burbank et al, Banik et al, and Bryan et al to have the sample tube advancement assembly comprise a vacuum chamber and a floating piston as taught by Terwilliger as an equally as effective advancement mechanism to sample the tissue.

Response to Arguments

Applicant's arguments filed 3/19/2009 have been fully considered but they are not persuasive. Applicant contends that the use of Burbank et al to teach the sample tube having a vacuum lumen and a sample lumen is improper. However, it is noted that Burbank et al teach the use of the dual lumens to effectively provide uniform vacuum to draw in the tissue samples. Thus, when this is applied to the combination of references above that include a sample tube, it would be obvious to have the sample lumen with the vacuum lumen structure to provide the advantages associated thereinwith. The feature of the dual lumens is already taught by Burbank as well as the need for vacuum within a sampling lumen. The sample tube is also taught by the combination of references above. Therefore, because all the claimed elements were known in the prior art, one of ordinary skill in the art could have combined the elements as claimed by

known methods with no change in their respective functions to yield a combination with predictable results for the reasons elaborated above.

39. It is also noted it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, it is noted that for a proper §103 rejection, "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). "There is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (Ruiz at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (National Steel Car v. Canadian Pacific Railway Ltd., 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004))." See MPEP 2143.01. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969.

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736